EXPERT OPINION IN THE CASE OF UNITED STATES OF AMERICA

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JOEL ADAMS SMITHERS DO

Date of Report: April 28, 2019
Arnold Feldman MD

Background and Experience

My name is Dr. Arnold Feldman. I am a Harvard trained physician specializing in Anesthesiology and Pain management whose career spans almost four decades. My training and experience include Endoscopic minimally invasive surgery of the spine, implantation of Spinal Devices including intrathecal delivery systems and Electrical stimulation systems for the treatment of spasticity and pain.

My experience includes virtually every type of spinal and epidural injection as well as facet injections of the lumbar, thoracic and cervical spine. I likely have performed 50 to 100,000 injections over the course of my career.

In the field of surgical anesthesia, I have participated in at least 50,000 surgical procedures and have developed anesthesia programs in multiple hospitals and surgical centers.

I began one of the first formal pain programs in the states of Alabama and Mississippi and was the first physician to implant a spinal medication delivery system 2 states In America.

In addition, I have had the opportunity to teach surgical technique to physicians from America, Germany, France, Mexico, Korea, Canada and China.

I am the inventor of surgical instrumentation systems for spinal surgery which treat spinal pain.

In the clinic setting, I have conservatively seen 50,000 patients over the years for the treatment of intractable pain (chronic Pain) and am expert in this setting as well.

I have been named as an expert in my field in both Federal and State courts and have served as Deputy coroner in Mississippi and as physician for the Sheriff's Department in Adams County

Mississippi as well as having served on the Governors counsel on malpractice reform under then Governor Haley Barbour.

I have been a laboratory director since 1997 and am expert in toxicology in the clinical setting.

In addition, I am highly trained in Mri and Ct scan, having interpreted thousands for my patients over my career and having operated high Field and Open MRI scanners and Multislice CT Scanners.

I have had the honor of treating thousands of patients from all walks of life. I have been dedicated to them and the field of medicine for most of my life.

I begin my Expert opinion report with a selection from the World Health Organization List of essential medicines:[1]

20th edition

WHO Model List of Essential Medicines (March 2017) Explanatory notes

The core list presents a list of *minimum medicine needs for a basic health-care system*, listing the most efficacious, safe and cost–effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment.

On page 2 of the List of essential medicines the World Health Organization Lists morphine, hydromorphone and oxycodone as essential medicine.

[1] http://www.who.int/medicines/publications/essentialmedicines/en/

Secondly, I will present the accepted definition of pain:

> **Pain is an unpleasant sensory and emotional experience that is associated with actual or potential tissue damage or described in such terms. Inherent in the definition is that pain is always subjective. The fundamental distinction between pain and nociception emphasizes the importance of the interpretation by experienced individual to assess the presence and intensity of pain and distress.**[2]

Thirdly I will List the requirements for a valid prescription according to the drug enforcement agency.

SECTION IX – VALID PRESCRIPTION REQUIREMENTS / DEA

To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are described in this section. A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (i.e., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number.

The prescription must also include:

1. Drug name
2. Strength
3. Dosage form
4. Quantity prescribed
5. Directions for use
6. Number of refills authorized (if any)

A prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. **An individual (i.e., secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature. The practitioner is responsible for** ensuring the prescription conforms to all requirements of the law and regulations, both federal and state. (from Deadiversion.usdoj.gov)

A. Where a prescription contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date. In addition, when filling any prescription for a controlled substance, *a pharmacist who fills multiple prescriptions issued in accordance with this regulation has a corresponding responsibility to ensure that each sequential prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a). (from Deadiversion.usdoj.gov)*

[2] International Association for the Study of Pain

Fourthly I would like to notice the court of RECENT CRITICALLY IMPORTANT FACTS:
1. The April 5, 2018 centers for disease control (CDC)over estimates of the Prescription related mortality because of the misapplication of statistical methods.
2.THE AMA (the American Medical Association) statement regarding the CDC guidelines and the negative effects of misapplication of these guidelines on patients.
3.The FDA warning about sudden discontinuation of opioids and the harm both potential and real of the removal of opiates and the legitimacy of opiates for the treatment of chronic intractable pain.

CDC Opioid Overdose Death Rates Over-Reported by Half

April 5, 2018

Agency says inflated estimates were caused by blurred lines between prescription and illicit opioids

A PPM Brief

Four researchers at the US Centers for Disease Control and Prevention (CDC)[1] have published an editorial that outlines how the agency's tracking methods and tallies of prescription opioid deaths have been deemed overestimated and inaccurate. The agency announced that the introduction of illicit fentanyl and other synthetic black-market opioids have been incorrectly counted as prescription drug deaths, affecting the total count reported.

"Traditionally, the CDC and others have included synthetic opioid deaths in estimates of 'prescription' opioid deaths," the researchers wrote. "However, with IMF (illicitly manufactured fentanyl) likely being involved more recently, estimating prescription opioid–involved deaths with the inclusion of synthetic opioid–involved deaths could significantly inflate estimates."

I would bring to the attention of the court the **April 9, 2019** FDA safety warning to all physicians.

FDA identifies harm reported from sudden discontinuation of opioid pain

medicines and requires label changes to guide prescribers on gradual, individualized tapering

FDA Drug Safety Communication

Similarly, the American Medical Association it is January 16 sixteenth letter

States:

"Inappropriate Use" of CDC guidelines should stop[3]

https://www.painnewsnetwork.org/stories/2018/11/14/ama-calls-for-misapplication-of-cdc-opioid-guideline-to-end.

I have been asked to review and comment as an expert for the defense of Joel Smithers. I was provided with a single USB drive on Monday April 22, 2019 at approximately 3 PM. I have reviewed within the extremely short time allotted the contents of the USB drive and my opinions are based on my Long and extensive experience in the field and I reserve the right to supplement my review for the court as new information becomes available to me.

The indictment begins with a list of medications taken from Dr. Smithers and implies that these for were meant for illegal distribution wherein there is no evidence support this allegation. In fact, April 27, 2019 was actually advertised as National Rx Takeback day. [4]Kroger and Food Lion as well as Walmart were listed as collection sites for individuals to collect medications that may have not been prescribed for them and to transport them to public locations such as grocery stores for the Martinsville area according to the DEA website search tool. These individuals have collected controlled substances from family members, relatives, deceased individuals and friends and are permitted to collect and transport them to law enforcement. The advertised time of

[3] Nov 14, 2018 Letter to HHS secretary

[4] Deadiversion.usdoj.gov April 28, 2019

collection is only 4 hours between the hours of 10 am and 2 pm. This requires collection, packaging, storage and transportation which has to occur before. How is this any different that the accused who was exercising recommended practice of disposal to law enforcement. Only he, a physician was charged.

Regarding counts 2 through 862 I have relied on the records provided to me as well as the 2 expert reports, one from Deeni Bassam Md and the other from Stacey L. Hail MD.

I will discuss Dr. Bassam's report first.

Dr. Bassam makes the following references:

1.Pateints traveled from Out of state

2.Patients were seen on a cash basis

3.There are deficiencies on documentation

4. There are red flags

5. There are no objective findings.

Martinsville Virginia a city of 13821[5] is 48 miles from Greensboro North Carolina, 46 miles from Winston-Salem North Carolina, 82 miles from Princeton West Virginia. Its main hospital is owned and operated by Sovah Health which maintains widely separated hospitals and clinics in Martinsville, Danville and Chatham Virginia. It is absolutely ***normal for patients to travel considerable distances*** to see a physician in Virginia and rural states. Therefore, the statement that patients cannot or should not travel across state lines is incorrect and misleading. Every American has a right to see a doctor of their choice. Strictly speaking it is our right according to the constitution.

> **Freedom** of movement under United States law. **Freedom** of movement under United States law is governed primarily by the Privileges and Immunities Clause of the United States Constitution which states, "The Citizens of each State shall be entitled to all Privileges and Immunities of Citizens in the several States."[6]
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> Regarding collecting payment from a patient:

[5] 2010 census

[6] The Constitution of United States of America

It is a felony to routinely **waive copays**, coinsurance, and deductibles for patients. As a general rule, a provider should not generally waive co-payments or deductibles. Moreover, in the case of Medicare and Medicaid patients, a provider should never waive or discount co-payments and deductibles unless the patient demonstrates financial hardship. [7]

The expert for the government states that there are significant deficiencies and documentation of appropriate medical necessity for the use of controlled substances. The definition of pain by the ***International Association for the Study of Pain*** makes it clear that the report of pain is subjective and can only be experienced by the patient. What this means is that any Doctor who is listening to a patient during the visit must realize that the most important portion of the pain exam is the report of pain from the patient. What must be understood is that there is no patho-anatomic finding for pain as there is for a heart attack on an EKG or a chest x-ray for pneumonia. What this means is that the self-report of pain is of primary importance and diagnostic studies such as x rays, cardiogram or physical examination must be relegated to confirming but never excluding the report of severe pain. This is absolute. There is no debate.

This also is incorrect because the DEA under their own authority allows the physician to prescribe 90 days of a schedule 2 controlled substances to a patient by the issuance of multiple prescriptions dated and signed and with a May fill. date. On the DEA diversion website, they List examples. A notable example is that of a doctor who wishes to issue a 90 Day supply of medication by issuing 9 prescriptions, then the doctor is within the law to give the patient these nine prescriptions pre-signed and issued on a single date. The patient may then take prescriptions to 2 through 9 to the pharmacy on the date for filling. No physical examination is required. No vital signs need to be taken nor face-to-face interview needs to be performed. No physical examination at all is required for the filling of 8 prescriptions for schedule 2 narcotics. It is from the DEA published website.

Is completely incongruous that the defendant is being criticized for seeing his patients regularly. Therefore, the expert Report issued by Dr. Bassam is incomplete, and must take into account these facts as well as the fact that it is now acceptable to transmit prescriptions electronically which may be done by a staff member or assistant to a pharmacy for schedule 2 medications. It is also acceptable for telemedicine to establish a relationship with a patient once and not see a patient for 24 months in a face-to-face visit. This expert report must be discounted as it is vague and largely incorrect.

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I have also had the opportunity to review the report of Stacey Hail MD. Dr. Hail has listed her credentials. Importantly, there is no mention of training and experience in

[7] Beckerasc.com

treating chronic pain patients. Her training is primary in emergency medicine which inherent in the field are short encounters often as a result of trauma and heart disease and often accompanied by alcohol and illicit substances. She states this clearly on page 1, paragraph 3:

"I am an expert in recognizing the signs and symptoms of intoxication from prescription medications alcohol and illicit substances."

On page 3 of the Report, airway, pulmonary, neurological and cardiovascular disease are listed in a table as frequent causes of death. Most specifically cardiomyopathy is listed as a cause of sudden death. The doctor goes on to mention that records were reviewed for serious underlying health problems and diseases if available. The qualification "if available" does not give assurances that a complete examination or autopsy was ever performed. A complete autopsy includes microscopy of tissues which can identify many of the diseases listed in table 1. Are we to assume that these were performed or does this cast reasonable doubt that they were?

Page 4 speaks of arrhythmia and electrical disturbance of the heart. The doctor opines that these can cause ***sudden death***. The doctor also states emphatically that many individuals who have arrhythmias have structurally normal hearts. Certainly, if an arrhythmia can occur in the absence of structural changes in the heart then certainly an arrhythmia can occur in the presence of heart disease even mild or moderate heart disease. Such is the case here. This must cast doubt which must be accounted for by the jury of the cause of death and as the doctor States the cause of death is often ruled out by a process of elimination. It Is the opinion of this reviewer that this does not meet the standard and there is reasonable doubt without going much further in the report?

However, the expert report states "postmortem changes render the assumptions of clinical pharmacology ***largely invalid*** and make the concentrations of measured in postmortem samples difficult or ***impossible***." How can anyone progress any further without walking with full knowledge through a legal minefield when considering our rights of the accused? The operative words here are invalid, difficult or impossible!

In view of the above consideration if one assumes that a conclusion must be drawn and according to page 7 of the expert report provided:

"the best classification for manner of death in death due to the misuse or abuse of opioids without any apparent intent for self-harm is ***accident."***

The definition of accident is ***an event that happens by chance or that is without*** apparent or deliberate cause.

Dr. Hail's expert report goes on to state that the patient had a history of chronic back pain, depression and anxiety and suicide attempts. She had filled her prescriptions which were of the appropriate strength and number and had also filled the prescription by Dr. Hassan for alprazolam which would not have been entered into the prescription monitoring database at that time. The patient was also on multiple other medications including Gabapentin Mirapex, Bupropion and Geodon. In Her toxicology, there 7-amino clonazepam which was not prescribed by any physician. Dr. Hail goes on to say that it is not clear whether clonazepam was ever prescribed. ***What is not clear must create reasonable doubt as to causation.***

From the review of Dr. Hale's report, it is clear that the causation for this patient's demise is not clear.

The patient clearly took medication that was not prescribed by any physician that we know of and had evidence of hypertensive cardiovascular disease. This is uncommon the 35-year-old and as Dr. Hale mentioned may be a cause of arrhythmia which would be undetectable and lethal. This again casts doubt on causation and an arrhythmia is a listed cause of sudden death in Dr. Hail's report.

In summary is clear that the patient had history of chronic pain which is deserving of treatment and care. The patient was prescribed medications which were appropriate in strength and number according to the FDA approved indication and the patient had metabolites of nonprescribed controlled substances which could not be attributed to Dr. Smithers. In addition, the patient had documented cardiac disease on autopsy which is uncommon in a 35-year-old and could not be detectable by any physical examination and by Dr. Hale's own admission cannot be detectable postmortem, therefore there is considerable doubt as to the exact causation of the decedent.

It is not possible to attribute this patient's death to Dr. Smithers.

In summary, after review of the data presented to me, as an expert with almost 4 decades of experience in this field, it is my opinion Dr. Smithers acted within the bounds of legitimate medical practice in practice within the law and I see no evidence to convict him.

Arnold E Feldman M.D.